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1.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
FEMALE	14 YEARS			NO DATA - NO DATA	ROMANIA

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
"it seems that" 2 days after immunisation died	Unknown cause of death	Death		SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable physician. This report was received via a Pfizer sales representative.

A 14-year-old female patient received BNT162B2 (COMIRNATY), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced "it seems that" 2 days after immunisation patient died. The patient died on an unspecified date. It was not reported if an autopsy was performed.

No follow-up attempts are possible. The information about lot number and expiration date cannot be obtained. No further information is expected.

Case Comments

Based on the current available limited information in the case provided, the causal association between the event of Death due to unknown cause and the use of suspect product BNT162B2 cannot be fully assessed. The case will be reassessed if additional information becomes available.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Lab Data: Unknown

Lab Data

Lab Narrative:

Test Name	Normal Value	Test Date	Test Result	Lab Comments

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				NO DATA	-		NO DATA			

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

1.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Product(s) and Event(s) Information

Suspect Product(s)	Event(s)	CDS	Latency Group	Rechallenge	Causality per Reporter	Causality per Company
BNT162B2	Death	N	Unknown	N/A	N/A	N/A

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Death	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	Y	SPONTANEOUS	PHYSICIAN				23-JUL-2021	

References

Reference Type	Reference ID	Reference Notes
LOCAL REFERENCE NO.	(b) (6)	
E2B COMPANY NUMBER	(b) (6)	

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Section Page: 1

2.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	12 YEARS			CAUCASIAN - NO DATA	ITALY

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
septic shock	Septic shock	Septic shock	08-JUL-2021	SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable physician downloaded from the European Medicines Agency (EMA) EudraVigilance-WEB, regulatory authority number (b) (6).
A 12-year-old male patient received bnt162b2 (COMIRNATY), dose 2 intramuscular, administered in deltoid right on 03Jul2021 20:31 (Lot Number: FE2707; Expiration Date: Oct2021) as DOSE 2, 0.3ML SINGLE for COVID-19 immunisation. Medical history included infantile cerebral palsy of the spastic tetraparesis type, epilepsy (symptomatic drug resistant), severe intellectual disability, gastroesophageal reflux, and respiratory infections. Concomitant medications included clobazam (FRISIUM); esomeprazole magnesium (LUCEN [ESOMEPRAZOLE MAGNESIUM]); valproate sodium (DEPAKIN). Historical vaccine included first dose of COMIRNATY on 12Jun2021 for COVID-19 immunisation. On 08Jul2021, the patient experienced septic shock which was considered serious (hospitalization, life threatening, death). Date of death reported as 03Aug2021. Patient was in resuscitation sedated with midazolam and hemodialysis; administration of merrem 760 mg, linezolid 1200 mg, fluconazole, urbason 40 mg, Rocefin 2 g, Zithromax 400 mg, Konakion 10 mg were initiated. The patient underwent lab tests and procedures which included Fibrin D dimer with unknown results; alanine aminotra

nsferase (normal range: 5- 40 IU/l): 904 IU/l, aspartate aminotransferase (normal range: 5- 40 IU/l): 341 IU/l, creatine kinase (normal range: 24- 170 IU/l): 4664 IU/l, lactate dehydrogenase (normal range: 120- 240 IU/l): 1792 IU/l, thromboplastin: 42.9 seconds, C-reactive protein (normal range: 0- 5 mg/l): 15.68 mg/l, myoglobin blood (normal range: 20- 72 ng/ml): 30000 ng/ml, thrombopenia (normal range: 140000- 440000 /mm3): 59.00 x10 /mm3, troponin (normal range: 0- 0.5 ng/ml): 104.64 ng/ml all on 08Jul2021; alanine aminotransferase: 3429 IU/l, aspartate aminotransferase: 946 IU/l, creatine kinase: 19627 IU/l and 10900 IU/l, lactate dehydrogenase: 5856 IU/l, thromboplastin: 35.40 seconds, C-reactive protein: 47.38 mg/l, myoglobin blood: 30000 ng/ml, thrombopenia: 68.00 x10 /mm3, troponin: 105.08 ng/ml all on 09Jul2021; thromboplastin: 145 seconds on 11Jul2021; creatine kinase: 3791 IU/l on 11Jul2021; alanine aminotransferase: 1727 IU/l, aspartate aminotransferase: 553 IU/l, creatine kinase: 253900 IU/l, lactate dehydrogenase: 4184 IU/l, C-reactive protein: 8.55 mg/l, myoglobin blood: 15013.00 ng/ml, thrombopenia: 41.00x10 /mm3 all on 12Jul2021. Aspartate aminotransferase on 09Jul2021 with result 904 u/l and range 5-40. Fibrin D dimer on 09Jul2021 with result 10900 ng/ml and range 0-270; Plateletcrit on 08Jul2

021 with result 104.64 ng/ml and range 0-0.5; Cardiac troponin on 08Jul2021 with result 3681 ng/L and range 1-14; Finding: septic shock. The outcome of the event was fatal. It is unknown if autopsy was done.

Reporter's comment: It should be noted that the patient is affected by infantile cerebral palsy of the spastic tetraparesis type, epilepsy (symptomatic drug resistant), severe intellectual disability, gastroesophageal reflux disease and respiratory infections.

Follow-up (06Sep2021): New information received from contactable physician downloaded from the European Medicines Agency (EMA) EudraVigilance- (b) (6) included: Lab data and death information.

Follow-up (17Sep2021): Follow-up attempts are completed. No further information is expected.

Lab Data:	Present	**Lab Data**

Lab Narrative:

Test Name	**Normal Value**	**Test Date**	**Test Result**	**Lab Comments**
Alanine aminotransferase	5 - 40	08-JUL-2021	* | 904 | IU/l	
Alanine aminotransferase	5 - 40	09-JUL-2021	* | 3429 | IU/l	
Alanine aminotransferase	5 - 40	12-JUL-2021	* | 1727 | IU/l	
Aspartate aminotransferase	5 - 40	08-JUL-2021	* | 341 | IU/l	

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2.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Test Name	Normal Value	Test Date	Test Result	Lab Comments
Aspartate aminotransferase	5 - 40	09-JUL-2021	* | 904 | IU/l	
Aspartate aminotransferase	5 - 40	09-JUL-2021	* | 946 | IU/l	
Aspartate aminotransferase	5 - 40	12-JUL-2021	* | 553 | IU/l	
Blood creatine phosphokinase	24 - 170	08-JUL-2021	* | 4664 | IU/l	
Blood creatine phosphokinase	24 - 170	09-JUL-2021	* | 10900 | IU/l	
Blood creatine phosphokinase	24 - 170	09-JUL-2021	* | 19627 | IU/l	
Blood creatine phosphokinase	24 - 170	11-JUL-2021	* | 3791 | IU/l	
Blood creatine phosphokinase	24 - 170	12-JUL-2021	* | 253900 | IU/l	
Blood lactate dehydrogenase	120 - 240	08-JUL-2021	* | 1792 | IU/l	
Blood lactate dehydrogenase	120 - 240	09-JUL-2021	* | 5856 | IU/l	
Blood lactate dehydrogenase	120 - 240	12-JUL-2021	* | 4184 | IU/l	
Blood thromboplastin		08-JUL-2021	* | 42.9 | seconds	
Blood thromboplastin		09-JUL-2021	* | 35.40 | seconds	
Blood thromboplastin		11-JUL-2021	* | 145 | seconds	
C-reactive protein	0 - 5	08-JUL-2021	* | 15.68 | mg/l	
C-reactive protein	0 - 5	09-JUL-2021	* | 47.38 | mg/l	
C-reactive protein	0 - 5	12-JUL-2021	* | 8.55 | mg/l	
Fibrin D dimer	0 - 270	09-JUL-2021	* | 10900 | ng/ml	
Fibrin D dimer	0 - 270		* | unknown results | ng/ml	
Myoglobin blood	20 - 72	08-JUL-2021	* | 30000 | ng/ml	
Myoglobin blood	20 - 72	09-JUL-2021	* | 30000 | ng/ml	
Myoglobin blood	20 - 72	12-JUL-2021	* | 15013.00 | ng/ml	
Plateletcrit	0 - 0.5		* | 104.64 | ng/ml	
Thrombocytopenia	140000 - 440000	08-JUL-2021	* | 59.00 x10 | /mm3	
Thrombocytopenia	140000 - 440000	09-JUL-2021	* | 68.00 x10 | /mm3	
Thrombocytopenia	140000 - 440000	12-JUL-2021	* | 41.00x10 | /mm3	
Troponin	0 - 0.5	08-JUL-2021	* | 104.64 | ng/ml	
Troponin	1 - 14	08-JUL-2021	* | 3681 | ng/L	
Troponin	0 - 0.5	09-JUL-2021	* | 105.08 | ng/ml	

2.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Suspect Product(s) Therapy Information

Suspect Product(s)	Unit Dose	Total Daily Dose	Regimen Dose	Route of Admin	Therapy Date(s)	Therapy Duration	Anatomical Location	Vaccination Dose No.	Lot No.	Batch No.
BNT162B2	.3 mL	.3 mL		INTRAMUSCULAR	03-JUL-2021 - 03-JUL-2021		DELTOID RIGHT	2	FE2707	

Suspect Product(s) Information

Suspect Product(s)	Indication(s)	Form of Admin	First Total Daily Dose	Action Taken	Dechallenge	Rechallenge	Interacting Drug
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION	.3 mL	NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information

Suspect Product(s)	Event(s)	CDS	Latency Group	Rechallenge	Causality per Reporter	Causality per Company
BNT162B2	Septic shock	N	Post Therapy	N/A	N/A	N/A

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes
PATIENT	Cerebral palsy			NO DATA	
PATIENT	Epilepsy			NO DATA	symptomatic drug resistant
PATIENT	Gastrooesophageal reflux disease			NO DATA	
PATIENT	Intellectual disability			NO DATA	severe
PATIENT	Respiratory tract infection			NO DATA	

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Septic shock	

ConMed: Present

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
CLOBAZAM	FRISIUM	-	NO DATA
ESOMEPRAZOLE MAGNESIUM	LUCEN [ESOMEPRAZOLE MAGNESIUM]	-	NO DATA
VALPROATE SODIUM	DEPAKIN	-	NO DATA

2.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Conmed Devices

Device Type	Model No.	Serial No.
NO DATA		

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	Y	SPONTANEOUS	PHYSICIAN				26-JUL-2021	

References

Reference Type	Reference ID	Reference Notes
E2B AUTHORITY NUMBER	(b) (6)	(b) (6)
E2B REPORT DUPLICATE	(b) (6)	(b) (6)

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

3.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	13 YEARS			NO DATA - NO DATA	MEXICO

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
13-year-old dies after receiving Pfizer vaccine	Unknown cause of death	Death		SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a non-contactable consumer received via a Pfizer sponsored program Instagram Pfizer Mexico. A 13-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), unknown dose number, via an unspecified route of administration on an unspecified date (Batch/Lot Number: unknown) as a single dose for COVID-19 immunisation. Medical history was not reported. Concomitant medications were not reported. It was reported that the 13-year-old patient died after receiving the BNT162B2 vaccine on an unspecified date. It was not reported if an autopsy was performed and the cause of death was not provided.

No follow-up attempts poss ble; information about lot/batch number cannot be obtained.

Lab Data: Unknown

Lab Data

Lab Narrative:

Test Name	Normal Value	Test Date	Test Result	Lab Comments

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				NO DATA	-		NO DATA			

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information						
Suspect Product(s)	**Event(s)**	**CDS**	**Latency Group**	**Rechallenge**	**Causality per Reporter**	**Causality per Company**
BNT162B2	Death	N	Unknown	N/A	N/A	N/A

Patient Medical History					
Patient/Parent Indicator	**Coded Condition**	**Start Date**	**Stop Date**	**Ongoing**	**Notes**

Cause of Death/Autopsy

Other Death Information:

3.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Death	

ConMed:	Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	N	SPONTANEOUS	NA				26-JUL-2021	

References

Reference Type	Reference ID	Reference Notes
NCSP	(b) (6)	
E2B COMPANY NUMBER	(b) (6)	

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Section Page: 1

4.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
FEMALE	15 YEARS	188.0	56.0	NO DATA - NO DATA	FRANCE

Event Information and Narrative

Verbatim Term	Lowest Level Term	Preferred Term	Onset Date	Event Seriousness	Clinical Outcome	Procedure Causality Per Company	Procedure Causality Per Reporter
Cardiac arrest/asystole	Cardiac arrest	Cardiac arrest	13-JUL-2021	SERIOUS	FATAL	NO DATA	NO DATA
Anoxia cerebral	Anoxia cerebral	Brain hypoxia		SERIOUS	FATAL	NO DATA	NO DATA
vegetative coma	Coma	Coma	30-JUL-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
retro-rolandic aspect of brain death	Brain death	Brain death	30-JUL-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
asthenia	Asthenia	Asthenia	11-JUL-2021	NONSERIOUS	UNKNOWN	NO DATA	NO DATA
arm pain	Pain in arm	Pain in extremity	11-JUL-2021	NONSERIOUS	UNKNOWN	NO DATA	NO DATA
headaches	Headache	Headache	12-JUL-2021	NONSERIOUS	UNKNOWN	NO DATA	NO DATA

This is a spontaneous report from a contactable physician downloaded from the European Medicines Agency (EMA) EudraVigilance- (b) (6)

A 15-year-old female patient received bnt162b2 (COMIRNATY), intramuscular on 11Jul2021 07:30 (Lot Number: Unknown) (at the age of 15-year-old) as dose 1, single for COVID-19 immunization. Medical history included ongoing asthma, ongoing Barlow's syndrome, ongoing Marfan's syndrome. The patient's concomitant medications were not reported. In good health overall, apart from a loss of 10kg over one year (since entering high school). During the day (11Jul2021), asthenia and isolated arm pain. The next day (12Jul2021), headaches yielding under Doliprane. On 13Jul2021, around 16:30 (last moment conscious view), her mother drops her off to her father. Father watered the garden and she cleaned the garage to prepare for her birthday party. On 13Jul2021 17:20, her father found her in cardio respiratory arrest, back to the ground, next to a ladder. No flow was unknown. At 17:30 arrival of firefighters: 2 external electric shocks were given and 1 mg of adrenaline injected. Moderately reactive pupils. At 17:50 arrival of Specialist mobile emergency unit: asystole (Life-threatening). Two injections of 1 mg of adrenaline, transition to ventricular fibrillation. 2

external electric shock, 2 ampule of Cordarone and one ampule of Calcium Gluconate. Return to regular sinus rythme without disturbance of repolarization and resumption of a pulse. Orotracheal intubation (probe no 6). New: 1 external electric shock, one ampule of Cordarone and 1 mg of adrenaline. Return of a sinus rhythm but presence of a sub ST in infero lateral. 90/60 mmHg arterial pressure excluding sedation. Tight areactive bilateral miosis pupils. Ventilated in Ventilator-Associated Conditions but presence of spontaneous ventilation requiring sedation by Hypnovel and Sufentanyl and 10 mg of Nimbex. Parallel introduction of Noradrenaline 0.8 mg/h. No filling. In total: low flow of 30 minutes. Recovered and transfer to intensive care. Examinations: biology: complete blood count normal, C-reactive protein 1.4. Coroner considered as normal no coronary dissection. Computed tomography scan Computed tomography arterial portography: No aortic dissection or large vsx, no intracranial bleeding, the super sigmoid aortography does not show any aortic insufficiency. The ascending aorta is moderately dilated. Computerised tomogram head: no bleeding, no traumatic injury. Electrocardiogram: Not very evocative. Respiratory rate. Maintenance of sedation, temperature control at 36 degrees. Complicated cardiac arrest of

a Takotsubo. Trans-thoracic echocardiography finding a 30% altered left ventricular ejection fraction with kinetic disorders suggestive of Takotsubo (post stress?). More doubt about intra-left ventricular thrombus. Low left ventricular filling pressures. Integral time speed= 8. Inferior vena cava= 15. 15Jul2021 Appearance in the morning of continual clonies of the multiple sulfatase deficiency, put under Keppra increased to 750x2. Electroencephalography results pending + Left transcranial doppler more disturbed than the right (Vdiastolic 20 vs 40 on the right), Control contrast enhanced computed tomography scan superimposable at the level of large vsx, but appearance of parenchymal parenchymal hemispherical hemispherical right upper cerebellar areas of ischemic appearance. 20Jul2021 pathological awakening, inhalation lung disease, myocarditis assessment in progress (negative). 23Jul2021 no sign of wakign up flat electroencephalogram alternating with a few waves of intermittent activity. Computered tomography scan stability of ischemic lesions appearance of cerebral edema compatible with anoxo-ischemic lesions, put under Mannitol. Cardio: cardiac magnetic resonance imaging in favor of a takotsubo, myocarditis unl kely, infective and immunological workup negative. 27Jul2021 Pathological electroencephalogram

4.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

, Keppra introduction. Computered tomography scan increase in cerebral edema reaching almost the entire sustentorial stage, sudden episodes of desaturation. The COVID serology returns positive (Ig G antiS and antiN and IgM), re-reading of the entry serology concluded with a Covid infection starting at the same time as the anti-covid vaccination. 30Jul2021 retro-rolandic aspect of brain death, vegetative coma. Decision to limit therapy. Complete file no further information. The patient died on 07Aug2021. An autopsy was not performed. Cause of Death: Anoxia cerebral and Cardiac arrest while outcome of the other events was unknown.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Lab Data:	Present	**Lab Data**

Lab Narrative:

Test Name	**Normal Value**	**Test Date**	**Test Result**	**Lab Comments**
Blood pressure increased		13-JUL-2021	* | 90/60 | mmHg	
Body temperature decreased		13-JUL-2021	* | 36 | Centigrade	
Computerised tomogram		13-JUL-2021	* | The ascending aorta is moderately dilated |	No aortic dissection or large vsx, no intracranial bleeding, the super sigmoid aortography does not show any aortic insufficiency
Computerised tomogram		15-JUL-2021	* | appearance of parenchymal parenchymal hemispherica |	appearance of parenchymal parenchymal hemispherical hemispherical right upper cerebellar areas of ischemic appearance
Computerised tomogram head		13-JUL-2021	* | no bleeding |	no traumatic injury
Computerised tomogram head		23-JUL-2021	* | stability of ischemic |	lesions appearance of cerebral edema compatible with anoxo-ischemic lesions, put under Mannitol
Computerised tomogram head		27-JUL-2021	* | increase in cerebral edema |	reaching almost the entire sustentorial stage, sudden episodes of desaturation.
C-reactive protein		13-JUL-2021	* | 1.4 |	
Echocardiogram			* | finding a 30% |	altered left ventricular ejection fraction with kinetic disorders suggestive of Takotsubo
Electrocardiogram		13-JUL-2021	* | Not very evocative |	Respiratory rate
Electroencephalogram		23-JUL-2021	* | flat |	with a few waves of intermittent activity
Electroencephalogram		27-JUL-2021	* | Pathological |	Keppra introduction
Full blood count		13-JUL-2021	* | normal |	
Magnetic resonance imaging		13-JUL-2021	* | cardio |	in favor of a takotsubo
SARS-CoV-2 ant body test positive		13-JUL-2021	POSITIVE | positive |	(Ig G antiS and antiN and IgM), re-reading of the entry serology concluded with a Covid infection starting at the same time as the anti-covid vaccination
Ultrasound Doppler		13-JUL-2021	* | left more disturbed |	than the right (Vdiastolic 20 vs 40 on the right)

Suspect Product(s) Therapy Information

Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				INTRAMUSCULAR	11-JUL-2021 - 11-JUL-2021		NO DATA	1	Unknown	

4.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Suspect Product(s) Information

Suspect Product(s)	Indication(s)	Form of Admin	First Total Daily Dose	Action Taken	Dechallenge	Rechallenge	Interacting Drug
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information

Suspect Product(s)	Event(s)	CDS	Latency Group	Rechallenge	Causality per Reporter	Causality per Company
BNT162B2	Cardiac arrest	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Brain hypoxia	N	Unknown	N/A	N/A	N/A
BNT162B2	Coma	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Brain death	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Asthenia	Y	Pre-Therapy	N/A	N/A	N/A
BNT162B2	Pain in extremity	Y	Pre-Therapy	N/A	N/A	N/A
BNT162B2	Headache	Y	Post Therapy	N/A	N/A	N/A

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes
PATIENT	Asthma			ONGOING	
PATIENT	Marfan's syndrome			ONGOING	
PATIENT	Mitral valve prolapse			ONGOING	

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Brain hypoxia	
DEATH	PATIENT	Cardiac arrest	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

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4.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	Y	SPONTANEOUS	PHYSICIAN				16-AUG-2021	

References

Reference Type	Reference ID	Reference Notes
E2B AUTHORITY NUMBER	(b) (6)	(b) (6)
E2B REPORT DUPLICATE	(b) (6)	(b) (6)

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Section Page: 1

5.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	13 YEARS	140.0	32.0	NO DATA - NO DATA	GERMANY

Event Information and Narrative

Verbatim Term	Lowest Level Term	Preferred Term	Onset Date	Event Seriousness	Clinical Outcome	Procedure Causality Per Company	Procedure Causality Per Reporter
Disseminated intravascular coagulation	Disseminated intravascular coagulation	Disseminated intravascular coagulation	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
Lung hemorrhage	Lung hemorrhage	Pulmonary haemorrhage	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
Pyrexia	Pyrexia	Pyrexia	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
Multiorgan failure	Multiorgan failure	Multiple organ dysfunction syndrome	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
Septic shock	Septic shock	Septic shock	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
haemorrhagic hemithorax	Thoracic haemorrhage	Thoracic haemorrhage	---AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
massive liver failure	Liver failure	Hepatic failure	---AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
creatinine elevated	Blood creatinine increased	Blood creatinine increased	---AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
bleeding in bladder and abdomen	Intra-abdominal bleeding	Intra-abdominal haemorrhage	---AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
bleeding in bladder and abdomen	Urinary bladder bleeding	Urinary bladder haemorrhage	---AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
anuria	Anuria	Anuria	---AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
respiratory insufficient	Respiratory failure	Respiratory failure	13-AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
epilepticus	Status epilepticus	Status epilepticus		SERIOUS	UNKNOWN	NO DATA	NO DATA
At admission the platelets were 150.000/ml and declined to 53.000/ml	Platelets decreased	Platelet count decreased	13-AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
Inappropriate schedule of vaccine administered	Inappropriate schedule of vaccine administered	Inappropriate schedule of product administration	11-AUG-2021	NONSERIOUS	UNKNOWN	NO DATA	NO DATA

5.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

This is a spontaneous report from a non-contactable other HCP downloaded from the European Medicines Agency (EMA) EudraVigilance- (b) (6) . A 13-year-old male patient received second dose of bnt162b2 (COMIRNATY, Solution for Injection, Lot Number: 10020A) via an unknown route of administration on 11Aug2021 (at the age of 13-year-old) as dose 2, 0.3 ml single for COVID-19 immunization. The patient's medical history included extremely preterm (less than 28 weeks), Hypox-ic-ischaemic encephalopathy, posthaemorrhagic hydrocephalus, symptomatic epilepsy, dysphagia, respiratory insufficiency, reflux oesophagitis on an unspecified date. The patient born at gestation 24+4 with Grad iV (right) and Grad II (left) intra cranial heamorrage. Further complication post-natal were broncho pulmonal dysplasia including implementing a liquor shunt. Further complication was a treatment resistant epilepsy despite long term treatment with Valproate. Regular control of liver function ware performed without major deteriation (last control 2 weeks prior to death). At the age of ten year the patient received a repair of the gastroesophageal reflux and which appeared to be solved since. In addition, the patient received a major hip operation for hipdyplasia, exact timepoint of the surgery is following. The patient previously

received first dose of bnt162b2 (COMIRNATY, Formulation: Solution for Injection) dose 1, Batch/Lot number unknown) for COVID-19 immunisation on 16Jun2021. Concomitant medications were not reported. The patient underwent lab tests and procedures which included platelets min 3410x 31uml, Quick <10, INR>4.9, pTT >180 sec, proBNP 24937 pg/ml, Trop T 1580 pg/ml on an unknown date. The patient experienced multiorgan failure, lung hemorrhage, disseminated intravascular coagulation, pyrexia and septic shock on 13Aug2021. The patient died on 14Aug2021. Seriousness for the events was reported as death, hospitalization and life threatening. At admission on the 13Aug2021 the patient was respiratory insufficient and needed intubation and ventilation. At admission the platelets were 150.000/ml and declined to 53.000/ml after app. 12h treatment. In addition, the coagulation system deteriorated and finally the patient appeared with a haemorrhagic hemithorax which eventually lead to death of the patient. Status epilepticus on admission. So far about 1-2 seizures per month, seizures also always during fever. Therapy with IVIG and cortisone. In the course of the disease massive liver failure, anuria, creatinine elevated, bleeding in bladder and abdomen. The Autopsy was not performed. The full Hospital letter with additional detai

ls will follow. Outcome of multiorgan failure, lung hemorrhage, disseminated intravascular coagulation, pyrexia and septic shock, Thoracic haemorrhage was fatal, outcome of other events was unknown. Relatedness of drug to reaction(s)/event (s) Source of assessment PEI. Result of Assessment D. Unclassifiable.

Sender Comment: Platelets min 3410^31uml, Quick <10, INR>4,9; pTT >180 sec, proBNP 24937 pg/ml, Trop T 1580 pg/ml. Inflammatory parameters not elevated. CSF examination with shunt in place blande, no signs of meningitis. Blood culture results not yet available. Status epilepticus on admission. So far about 1-2 seizures per month, seizures also always during fever. Therapy with IVIG and cortisone.

No follow-up attempts poss ble. No further information expected.

Follow-up (23Aug2021 and 24Aug2021): New information received from a non-contactable other HCP downloaded from the European Medicines Agency (EMA) EudraVigilance- (b) (6) included: new events (liver failure, anuria, creatinine elevated, bleeding in bladder and abdomen, haemorrhagic hemithorax, respiratory insufficient, the platelets were 150.000/ml and declined to 53.000/ml, Status epilepticus), lab tests, medical history, Autopsy (not performed), death cause (haemorrhagic hemithorax).

Follow-up (30Aug2021): New information r

eceived from product quality complaints department included: no investigation could be performed due to batch/lot no. provided within source doc was not found to be valid.

No follow-up attempts poss ble. No further information expected.

Lab Data:	Present	**Lab Data**

Lab Narrative:

Test Name	**Normal Value**	**Test Date**	**Test Result**	**Lab Comments**
Activated partial thromboplastin time			* | >180 | seconds	
Amniotic fluid index			* | shunt in place blande, no signs of meningitis |	
Blood culture			* | Not yet avalaiable |	
International normalised ratio			* | 4.9 |	
Liver function test			* | with out major deteriation |	
N-terminal prohormone brain natriuretic peptide			* | 24937 | pg/mL	

5.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Test Name	Normal Value	Test Date	Test Result	Lab Comments
Platelet count		13-AUG-2021	* | 150.000 |	/ml
Platelet count		13-AUG-2021	* | 53.000 |	/m
Platelet count			* | 3410^31 |	min 3410x31uml
Prothrombin time			* | <10 |	
Troponin T			* | 1580 | pg/mL	

Suspect Product(s) Therapy Information

Suspect Product(s)	Unit Dose	Total Daily Dose	Regimen Dose	Route of Admin	Therapy Date(s)	Therapy Duration	Anatomical Location	Vaccination Dose No.	Lot No.	Batch No.
BNT162B2	.3 mL	.3 mL		NO DATA	11-AUG-2021 - 11-AUG-2021	1 DAY(S)	NO DATA	2	10020A	

Suspect Product(s) Information

Suspect Product(s)	Indication(s)	Form of Admin	First Total Daily Dose	Action Taken	Dechallenge	Rechallenge	Interacting Drug
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION	.3 mL	NOT APPLICABLE	N/A	N/A	NO DATA

5.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Product(s) and Event(s) Information						
Suspect Product(s)	**Event(s)**	**CDS**	**Latency Group**	**Rechallenge**	**Causality per Reporter**	**Causality per Company**
BNT162B2	Disseminated intravascular coagulation	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Pulmonary haemorrhage	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Pyrexia	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Multiple organ dysfunction syndrome	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Septic shock	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Thoracic haemorrhage	N	Unknown	N/A	N/A	N/A
BNT162B2	Hepatic failure	N	Unknown	N/A	N/A	N/A
BNT162B2	Blood creatinine increased	N	Unknown	N/A	N/A	N/A
BNT162B2	Intra-abdominal haemorrhage	N	Unknown	N/A	N/A	N/A
BNT162B2	Urinary bladder haemorrhage	N	Unknown	N/A	N/A	N/A
BNT162B2	Anuria	N	Unknown	N/A	N/A	N/A
BNT162B2	Respiratory failure	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Status epilepticus	N	Unknown	N/A	N/A	N/A
BNT162B2	Platelet count decreased	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Inappropriate schedule of product administration	Y	<= 1 day	N/A	N/A	N/A

Patient Medical History

5.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes
PATIENT	Bronchopulmonary dysplasia			NO DATA	
PATIENT	Dysphagia				
PATIENT	Epilepsy				
PATIENT	Gastrooesophageal reflux disease				
PATIENT	Haemorrhage intracranial			NO DATA	born at gestation 24+4 with Grad iV (right) and Grad II (left) intra cranial heamorrage
PATIENT	Hip deformity			NO DATA	
PATIENT	Hip surgery			NO DATA	
PATIENT	Hypoxic-ischaemic encephalopathy				
PATIENT	Posthaemorrhagic hydrocephalus				
PATIENT	Premature baby				
PATIENT	Respiratory failure				

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Disseminated intravascular coagulation	
DEATH	PATIENT	Multiple organ dysfunction syndrome	
DEATH	PATIENT	Pulmonary haemorrhage	
DEATH	PATIENT	Pyrexia	
DEATH	PATIENT	Septic shock	
DEATH	PATIENT	Thoracic haemorrhage	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

5.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required,Life Threatening,Medically Significant

Report History								
Source	**HP/Medically Confirmed**	**Case Report Type**	**Reporter Occupation**	**Protocol/Study No.**	**Center ID & Other ID**	**Patient ID**	**Initial Safety Receipt Date**	**EUDRACT No.**
Spontaneous	Y	SPONTANEOUS	OTHER HEALTH PROFESSIONAL				19-AUG-2021	

References		
Reference Type	**Reference ID**	**Reference Notes**
E2B AUTHORITY NUMBER	DE-PEI-202100168078	PEI
E2B REPORT DUPLICATE	DE-PEI-202100168078	PEI
PRODUCT COMPLAINT NO.	6284782	CITI PR ID
PRODUCT COMPLAINT NO.	INT-183670	INT ID

Parent Medical History					
Patient/Parent Indicator	**Coded Condition**	**Start Date**	**Stop Date**	**Ongoing**	**Notes**

Section Page: 1

6.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	15 YEARS			NO DATA - NO DATA	AUSTRIA

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
Death/NOS death	Unknown cause of death	Death	20-JUL-2021	SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable physician downloaded from the European Medicines Agency (EMA) EudraVigilance-WEB Regulatory Authority number (b) (6). A 15-year-old male patient received bnt162b2 (COMIRNATY), dose 1 intramuscular on 01Jul2021 (Batch/Lot Number: FD6840) as dose 1, single for covid-19 immunisation. The patient medical history and concomitant medications were none. Patient was found dead in bed on the morning of 20Jul2021. There were no known previous illnesses. The forensic autopsy could not find a cause of death until today. Also reported on 20Jul2021 the patient experienced death/NOS death. An autopsy was performed, and results were not provided.

Sender Comment: BASGAGES-comment: Follow-up information has been requested. Comirnaty/ Death NOS/ Health Care Professional/ WHO Assessment/ Possible.

No follow-up attempts are possible. No further information is expected.

Lab Data:	Unknown	**Lab Data**

Lab Narrative:

Test Name	**Normal Value**	**Test Date**	**Test Result**	**Lab Comments**

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				INTRAMUSCULAR	01-JUL-2021 - 01-JUL-2021	1 DAY(S)	NO DATA	1	FD6840	FD6840

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information						
Suspect Product(s)	**Event(s)**	**CDS**	**Latency Group**	**Rechallenge**	**Causality per Reporter**	**Causality per Company**
BNT162B2	Death	N	Post Therapy	N/A	N/A	N/A

Patient Medical History					
Patient/Parent Indicator	**Coded Condition**	**Start Date**	**Stop Date**	**Ongoing**	**Notes**

6.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Death	

ConMed: None

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	Y	SPONTANEOUS	PHYSICIAN				23-AUG-2021	

References

Reference Type	Reference ID	Reference Notes
E2B AUTHORITY NUMBER	(b) (6)	(b) (6)
E2B REPORT DUPLICATE	(b) (6)	(b) (6)
PRODUCT COMPLAINT NO.	(b) (6)	(b) (6)
PRODUCT COMPLAINT NO.	(b) (6)	(b) (6)

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

7.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	15 YEARS			ASIAN - NO DATA	JORDAN

Event Information and Narrative

Verbatim Term	Lowest Level Term	Preferred Term	Onset Date	Event Seriousness	Clinical Outcome	Procedure Causality Per Company	Procedure Causality Per Reporter
respiratory and circulatory failure	Respiratory failure	Respiratory failure	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
respiratory and circulatory failure	Circulatory failure	Circulatory collapse	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable consumer (parent, father of patient). A 15-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via unspecified route of administration, administered in the left arm on 09Aug2021 at 09:00 am (batch/lot number FF2154 and expiry date unknown) at 15 years of age as dose 1, single for covid-19 immunisation. The patient's medical history and concomitant medications were not provided. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient prior to vaccination, was not diagnosed with COVID-19. On 13Aug2021 at 04:30, the patient passed away without any history of illness. On 05Sep2021, the reporter informed that it was reported that the reason for death on the report was respiratory and circulatory failure (13Aug2021 at 04:30). The event resulted in emergency room/department or urgent care. The patient since the vaccination, had not tested for COVID-19. The patient had no treatment received. The outcome of the events was fatal. The reporter informed that it was not reported if an autopsy was performed. The patient was scheduled the second dose on 31Aug21. On 09Sep2021, the investigational results for the product description: compound bnt 162 covid-19 vaccine suspension for intramu

scular 2ml multiple dose vial x 1, lot # and expiration date: FF2154, Oct2021 with description of complaint: product quality investigation request: request for investigations for vaccine case per medical judgement for fatal event for lot number: FF2154 reasonably suggest device malfunction: no; severity of harm was not applicable, site sample status was not received. The summary of investigations was no related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation and stability. The PGS Puurs conclude that the reported defect is not representative of the quality of the batch and the batch remains acceptable. The NTM process determined that no regulatory notification was required. No corrective or preventive actions were identified as all reviewed records for the involved batch indicated that the batch met the established requirements at time of release. Final confirmation status: not confirmed; root cause: non-assignable (complaint not confirmed).

Follow-up (05Sep2021): New information received from the patient's father included: death certificate and the initial report for autopsy (final report not yet issued) were shared. The batch number was FF2154. The reason for death on the report was respiratory and circulatory failure added.

Follow-

up (09Sep2021): New information received from Pfizer Product Quality Group included: suspect drug data (expiry date), investigational results.

No follow-up attempts are needed. No further information is expected.

Lab Data: Unknown **Lab Data**

Lab Narrative:

Test Name	Normal Value	Test Date	Test Result	Lab Comments

Suspect Product(s) Therapy Information

Suspect Product(s)	Unit Dose	Total Daily Dose	Regimen Dose	Route of Admin	Therapy Date(s)	Therapy Duration	Anatomical Location	Vaccination Dose No.	Lot No.	Batch No.
BNT162B2				NO DATA	09-AUG-2021 - 09-AUG-2021		ARM LEFT	1	FF2154	

7.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

Suspect Product(s) Information

Suspect Product(s)	Indication(s)	Form of Admin	First Total Daily Dose	Action Taken	Dechallenge	Rechallenge	Interacting Drug
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information

Suspect Product(s)	Event(s)	CDS	Latency Group	Rechallenge	Causality per Reporter	Causality per Company
BNT162B2	Respiratory failure	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Circulatory collapse	N	Post Therapy	N/A	N/A	N/A

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Circulatory collapse	
DEATH	PATIENT	Respiratory failure	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	N	SPONTANEOUS	NA				29-AUG-2021	

7.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

References		
Reference Type	**Reference ID**	**Reference Notes**
COVAES REFERENCE NO.	(b) (6)	
E2B COMPANY NUMBER	(b) (6)	
PRODUCT COMPLAINT NO.	(b) (6)	(b) (6)
PRODUCT COMPLAINT NO.	(b) (6)	(b) (6)

Parent Medical History					
Patient/Parent Indicator	**Coded Condition**	**Start Date**	**Stop Date**	**Ongoing**	**Notes**

8.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	15 YEARS			NO DATA - NO DATA	SPAIN

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
Sudden death unexplained	Sudden death unexplained	Sudden death	09-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
Cardiorespiratory arrest	Cardio-respiratory arrest	Cardio-respiratory arrest	09-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable physician downloaded from the European Medicines Agency (EMA) EudraVigilance- (b) (6) . A 15-year-old male patient received unknown dose of bnt162b2 (COMIRNATY, Solution for injection, Lot number: unknown), via an unspecified route on 02Aug2021 as a single do tion. The patient has no prior history medical history. The patient concomitant medications were not reported. On 09Aug2021 at 09:02, with no prior pathology family found the patient without a pulse. Upon arrival of the emergency team, he has no pulse. Some stiffness of limbs. There is no prior Cardiorespiratory arrest. Time of evolution of Cardiorespiratory arrest is unknown. Judicial protocol is activated. Sudden death unexplained on 09Aug2021 00:00. It was unknown if autopsy has been done. The outcome of the events was fatal.

No follow-up attempts are possible, information on batch number cannot be obtained.

Lab Data:	Unknown	**Lab Data**

Lab Narrative:

Test Name	**Normal Value**	**Test Date**	**Test Result**	**Lab Comments**

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				NO DATA	02-AUG-2021 - 02-AUG-2021	1 DAY(S)	NO DATA	1	Unknown	

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information						
Suspect Product(s)	**Event(s)**	**CDS**	**Latency Group**	**Rechallenge**	**Causality per Reporter**	**Causality per Company**
BNT162B2	Sudden death	N	Post Therapy	N/A	N/A	N/A
BNT162B2	Cardio-respiratory arrest	N	Post Therapy	N/A	N/A	N/A

8.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Cardio-respiratory arrest	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	Y	SPONTANEOUS	PHYSICIAN				01-SEP-2021	

References

Reference Type	Reference ID	Reference Notes
E2B AUTHORITY NUMBER	(b) (6)	(b) (6)
E2B REPORT DUPLICATE	(b) (6)	(b) (6)

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

9.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	14 YEARS			NO DATA - NO DATA	SPAIN

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
pulmonary edema	Pulmonary edema	Pulmonary oedema	03-SEP-2021	SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a Pfizer-sponsored program "Pfizer Colleagues" Immediate Family and Household Vaccination Program - Spain, from a contactable consumer (patent's uncle) through the Pfizer company doctor.

A 14-year-old male patient received bnt162b2 (COMIRNATY), 1st dose on 06Jul2021 (Lot Number: EX0893) and 2nd dose on 27Jul2021 (Lot Number: EW2246, both via an unspecified route of administration as single dose for COVID-19 immunization. Medical history none. Concomitant medications were not reported. The patient experienced pulmonary edema (death) on 03Sep2021. The patient died on 03Sep2021. The autopsy revealed that the cause of death was pulmonary edema.

Lab Data:	Unknown	**Lab Data**

Lab Narrative:

Test Name	**Normal Value**	**Test Date**	**Test Result**	**Lab Comments**

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				NO DATA	06-JUL-2021 - 06-JUL-2021	1 DAY(S)	NO DATA	1	EX0893	
BNT162B2				NO DATA	27-JUL-2021 - 27-JUL-2021	1 DAY(S)	NO DATA	2	EW2246	

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information						
Suspect Product(s)	**Event(s)**	**CDS**	**Latency Group**	**Rechallenge**	**Causality per Reporter**	**Causality per Company**
BNT162B2	Pulmonary oedema	N	Post Therapy	N/A	N/A	N/A

Patient Medical History					
Patient/Parent Indicator	**Coded Condition**	**Start Date**	**Stop Date**	**Ongoing**	**Notes**

9.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Cause of Death/Autopsy			
Other Death Information:			
Type	**Patient/Parent Indicator**	**Coded Condition**	**Notes**
DEATH	PATIENT	Pulmonary oedema	

ConMed:	Unknown	Concomitant Product(s)	
Concomitant Product(s)	**Conmed Tradename As Reported**	**Therapy Date(s)**	**Route of Admin**
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	N	SPONTANEOUS	NA				07-SEP-2021	

References

Reference Type	Reference ID	Reference Notes
NCSP	(b) (6)	(b) (6)
E2B COMPANY NUMBER	(b) (6)	
PRODUCT COMPLAINT NO.	(b) (6)	(b) (6)
PRODUCT COMPLAINT NO.	(b) (6)	(b) (6)

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Section Page: 1

10.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	15 YEARS			NO DATA - NO DATA	GREECE

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
Sudden death	Sudden death	Sudden death	13-SEP-2021	SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable physician downloaded from the European Medicines Agency (EMA) EudraVigilance-WEB, regulatory authority number (b) (6)

A 15-year-old male patient received BNT162B2 (COMIRNATY), dose 1 intramuscular on 10Sep2021 (Batch/Lot Number: FG4442) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced sudden death on 13Sep2021. The patient died on 13Sep2021. An autopsy was performed and results were not provided.

No follow-up attempts poss ble. No further information expected.

Lab Data: Unknown

Lab Data

Lab Narrative:

Test Name	Normal Value	Test Date	Test Result	Lab Comments

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				INTRAMUSCULAR	10-SEP-2021 - 10-SEP-2021	1 DAY(S)	NO DATA	1	FG4442	

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information						
Suspect Product(s)	**Event(s)**	**CDS**	**Latency Group**	**Rechallenge**	**Causality per Reporter**	**Causality per Company**
BNT162B2	Sudden death	N	Post Therapy	N/A	N/A	N/A

Patient Medical History					
Patient/Parent Indicator	**Coded Condition**	**Start Date**	**Stop Date**	**Ongoing**	**Notes**

Cause of Death/Autopsy

Other Death Information:

10.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Sudden death	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	Y	SPONTANEOUS	PHYSICIAN				20-SEP-2021	

References

Reference Type	Reference ID	Reference Notes
E2B AUTHORITY NUMBER	(b) (6)	(b) (6)
E2B REPORT DUPLICATE	(b) (6)	(b) (6)
PRODUCT COMPLAINT NO.	(b) (6)	(b) (6)
PRODUCT COMPLAINT NO.	(b) (6)	(b) (6)

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Section Page: 1

11.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	12 YEARS	145.0	39.0	NO DATA - NO DATA	GERMANY

Event Information and Narrative

Verbatim Term	Lowest Level Term	Preferred Term	Onset Date	Event Seriousness	Clinical Outcome	Procedure Causality Per Company	Procedure Causality Per Reporter
Unknown cause of death	Unknown cause of death	Death	20-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
Pyrexia	Pyrexia	Pyrexia	20-AUG-2021	SERIOUS	NOT RECOVERED/NOT RESOLVED	NO DATA	NO DATA
Unwell	Unwell	Malaise	20-AUG-2021	SERIOUS	NOT RECOVERED/NOT RESOLVED	NO DATA	NO DATA
Dyspnoea	Dyspnoea	Dyspnoea	20-AUG-2021	SERIOUS	NOT RECOVERED/NOT RESOLVED	NO DATA	NO DATA

This is a spontaneous report from a consumer or other non hcp downloaded from the European Medicines Agency (EMA) EudraVigilance- (b) (6) and Sender's (Case) Safety Report Unique Identifier (b) (6)

Verbatim: This spontaneous report was received from a Consumer or other non health professional from Germany and concerns a patient (Male), age: 12 Year (born: unknown date). This report is serious - hospitalization. The patient's medical history and concurrent conditions included: no relevant medical history reported. The patient's weight was 39 kg, and height was 145 cm.
The patient was treated with Comirnaty (mRNA TOZINAMERAN), unknown dosage. Concomitant medications were: no concomitant medication reported. On 20Aug2021 the patient experienced Dyspnoea, Unknown cause of death. The patient's outcome was: not recovered/not resolved for Dyspnoea, fatal for Unknown cause of death.
Sender Comment: Are you or the person concerned known of any allergies? If yes, which? no
Information on risk factors or previous illnesses: none / malaise, fever, palpitations and shortness of breath. Up to cardiac arrest.
Result of assessment for events /PEI / : D. Unclassifiable

No follow-up attempts poss ble. Lot number cannot be obtained. No further information expected.

Lab Data:	Unknown	**Lab Data**

Lab Narrative:

Test Name	Normal Value	Test Date	Test Result	Lab Comments

Suspect Product(s) Therapy Information

Suspect Product(s)	Unit Dose	Total Daily Dose	Regimen Dose	Route of Admin	Therapy Date(s)	Therapy Duration	Anatomical Location	Vaccination Dose No.	Lot No.	Batch No.
BNT162B2				NO DATA	19-AUG-2021 - 19-AUG-2021	1 DAY(S)	NO DATA		Unknown	

11.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required

Suspect Product(s) Information

Suspect Product(s)	Indication(s)	Form of Admin	First Total Daily Dose	Action Taken	Dechallenge	Rechallenge	Interacting Drug
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information

Suspect Product(s)	Event(s)	CDS	Latency Group	Rechallenge	Causality per Reporter	Causality per Company
BNT162B2	Death	X	Post Therapy	N/A	N/A	N/A
BNT162B2	Pyrexia	X	Post Therapy	N/A	N/A	N/A
BNT162B2	Malaise	X	Post Therapy	N/A	N/A	N/A
BNT162B2	Dyspnoea	X	Post Therapy	N/A	N/A	N/A

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Cardiac arrest	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	N	SPONTANEOUS	NA				27-SEP-2021	

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11.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Hospitalization Required

References		
Reference Type	**Reference ID**	**Reference Notes**
E2B AUTHORITY NUMBER	(b) (6)	(b) (6)
E2B REPORT DUPLICATE	(b) (6)	(b) (6)
E2B REPORT DUPLICATE	(b) (6)	(b) (6)
E2B REPORT DUPLICATE	(b) (6)	(b) (6)

Parent Medical History					
Patient/Parent Indicator	**Coded Condition**	**Start Date**	**Stop Date**	**Ongoing**	**Notes**

Section Page: 1

12.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
FEMALE	12 YEARS			NO DATA - NO DATA	ITALY

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
Sudden death	Sudden death	Sudden death	---SEP-2021	SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable consumer, received via COVAES portal.
A 12-years-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as DOSE NUMBER UNKNOWN, SINGLE for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced sudden death (sudden death) on unspecified date in Sep2021. It was not reported if an autopsy was performed.

Additional information provided included:
Does Pfizer have permission to contact the reporter about this event?: Yes
Does Pfizer have permission to contact your/the patient's healthcare provider about this report?:No
Reason why batch/lot is Unknown: Not available/provided to reporter at the time of report completion
Did the patient receive any other vaccines within 4 weeks prior to the COVID vaccine:Unknown
Reported Event: Sudden death
Prior to vaccination, was the patient diagnosed with COVID-19?:Unknown
Since the vaccination, has the patient been tested for COVID-19?:Unknown

Follow-up (29Sep2021): additional information provided by the same contactable consumer included the following: The reporter was contacted as per the immediate follow-up activity of A

ER # (b) (6) (sudden death). She said she had no further information because she heard in a bar, people ta king about the event that happened to a 12-year-old girl. They said the girl was found dead in her bed by her parents about 3 weeks ago, the day after vaccination with BNT162B2 (unknown dose). She confirmed that she had no further information and was unable to obtain it.

No follow-up attempts are possible, information about batch/lot number cannot be obtained.

Lab Data:	Unknown	**Lab Data**

Lab Narrative:

Test Name	**Normal Value**	**Test Date**	**Test Result**	**Lab Comments**

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				NO DATA	-		NO DATA			

12.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Suspect Product(s) Information

Suspect Product(s)	Indication(s)	Form of Admin	First Total Daily Dose	Action Taken	Dechallenge	Rechallenge	Interacting Drug
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information

Suspect Product(s)	Event(s)	CDS	Latency Group	Rechallenge	Causality per Reporter	Causality per Company
BNT162B2	Sudden death	X	Unknown	N/A	N/A	N/A

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Sudden death	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	N	SPONTANEOUS	NA				28-SEP-2021	

References

Reference Type	Reference ID	Reference Notes
COVAES REFERENCE NO.	(b) (6)	

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Section Page: 1

13.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	13 YEARS			NO DATA - NO DATA	GERMANY

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
death	Death	Death		SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable physician and an Other Health Professional (Other HCP) based on information received by Pfizer from Biontech [manufacturer control number: 71619], license party for BNT162B2 (COMIRNATY). A 13-year-old male patient received the second dose of BNT162B2 (COMIRNATY) via an unspecified route of administration at single dose on an unspecified date for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient had died on an unspecified date. Reporter confirmed that the adverse event came up in video for a PMR project in Germany. Cause of death was not provided. It was unknown if an autopsy was performed. The outcome of event was fatal.

Follow-up (22Jul2021): New information reported includes: event details.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Case Comments

Based on the information currently available, a possible contributory role of the suspect vaccine BNT162B2 on causing the event death cannot be excluded.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Lab Data: Unknown **Lab Data**

Lab Narrative:

Test Name	Normal Value	Test Date	Test Result	Lab Comments

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				NO DATA	-		NO DATA	2		

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information						
Suspect Product(s)	**Event(s)**	**CDS**	**Latency Group**	**Rechallenge**	**Causality per Reporter**	**Causality per Company**
BNT162B2	Death	N	Unknown	N/A	N/A	N/A

13.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Death	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	Y	SPONTANEOUS	OTHER HEALTH PROFESSIONAL				07-JUL-2021	
	Y	SPONTANEOUS	PHYSICIAN					

References

Reference Type	Reference ID	Reference Notes
E2B REPORT DUPLICATE	(b) (6)	(b) (6)
LICENSE PARTNER NO.	(b) (6)	(b) (6)
E2B COMPANY NUMBER	(b) (6)	

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes